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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Andreas Hefel

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BAKER & DANIELS LLP
111 E. WAYNE STREET
SUITE 800
FORT WAYNE, IN 46802

EXAMINER

MAEWALL, SNIGDHA

ART UNIT

PAPER NUMBER

1612

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/780,152	HEFEL, ANDREAS	
	Examiner	Art Unit	
	Snigdha Maewall	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21, 23-26, 28, 29, 32, 34 and 35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21, 23-26, 28-29, 32 and 34-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Summary

1. Receipt of Applicant's Arguments/Remarks, amended claims and **RCE** filed on 06/19/09 is acknowledged.

Claims 1-20, 22, 27, 30-31 and 33 have been cancelled in this Application.

New claims 34-35 have been added.

Accordingly, claims **21, 23-26, 28-29, 32 and 34-35** are under prosecution.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims **21, 23-26, 28-29, 32 and 34-35** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 21 recites the limitation as a process of providing a human" which makes the claim indefinite because it is not clear the process of providing is oral or transdermal or intravenous. The nature of administration is not clear. Claims 21, 34 and 35 recite the limitation one or more specific needs, which makes the claim indefinite. It is not clear

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which specific need or how many need is the applicant referring to. The word need is ambiguous because it is not clear what disease or condition is the applicant referring to. Recitation of bonds in claim 25 renders the claim indefinite because the nature of bond is not clear and specific. The word solution without any specific component makes claim 29 indefinite, it is not clear whether the solution is in water or any other solvent. Recitation of and/or makes the claim indefinite because it is not clear whether the limitation is included or excluded. The metes and bounds of unsubstituted polysaccharide are not clear in claim 34. Regarding claim 28, it is not clear whether the polysaccharide molecules are surrounded by water outside the human body or the water envelope is formed in vivo once administered. Claims 21 and 24-25 recite method of providing first and second granular particle or gel which makes the claim indefinite. It is not clear whether the preparation is administered simultaneously or in sequential manner.

Appropriate correction is requested.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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5. Claims **21, 23, 25-26, 28-29, 32 and 34-35** are rejected under 35 U.S.C. 103(a) as being unpatentable over Shibata (EP 835654 A1).

Shibata teaches a method of producing a pharmaceutical preparation with sustained effect for oral administration of a pharmacologically active ingredient, the method comprising admixing a predetermined amount of said pharmacologically active ingredient with a predetermined amount of glucomannan (claim 4). The reference discloses that glucomannan makes a very viscous solution when dissolved in water and that glucomannan is not decomposed in the small intestine but is decomposed in the large intestine by *Escherichia coli* and loses its viscosity. The reference discloses the possibility of properly delaying absorption of a drug in the small intestine both by suppressing conveyance of the drug through the small intestine in the direction to the anus and suppressing diffusion of the drug in the solution (thus slowly released for resorption by the human or animal digestive system), both making use of the viscosity of the solution. As a result, the inventor has found that when glucomannan is orally administered together with a drug, gradual absorption of the drug occurred over a prolonged time period (thus increase of the nutrient-bio-availability of vital substances) compared with the case without administration of glucomannan, and that there is no reduction of overall absorption of the drug (thus separated from each other in their function) (page 2, lines 28-38). Thus, the present invention provides a pharmaceutical preparation with sustained effect for oral administration of a pharmacologically active ingredient comprising a mixture of said pharmacologically active ingredient and glucomannan (thus increase for improvement of wellbeing) (thus the embedded active

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substances are slowly released for resorption). In accordance with the present invention, the length of time during which the absorption of the pharmacologically active ingredient takes place may be conveniently controlled by simply adjusting the proportion of glucomannan to the amount of the active ingredient. Thus, the present invention allows sustainment of pharmacological effect of a variety of active ingredients orally administered to mammals including human (page 2, lines 38-44). Shibata further teaches the pharmaceutical preparation may be in any convenient form suitable to oral administration, such as a powder, granules, capsules, tablets, an aqueous preparation (page 3, lines 20-22).

It is to be noted that claims 25-26 and 28 provide the functional limitations once the active substance is introduced into human or animal, since the claimed compound is similar to the compound disclosed in the prior art, the functional limitations are considered to be associated with process.

The reference discloses that it is possible to combine two or more active ingredients with similar or different activities, see page 3, lines 18-20. The preparation also includes gel type preparation, it may be possible to add excipients and coloring material and binders for granules, see page 3, lines 20-25.

Based on the teachings of the prior art, it would have been within the purview of a skilled artisan to formulate a process of providing a human or animal a composition comprising two active ingredients which are functionally separated having none antagonistic interactions as taught by Shibata because Shibata teaches that it is possible to combine two or more active ingredients in the composition. Shibata also

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suggests making granules by adding excipients, as such it would have been within the purview of skilled artisan to make a matrix comprising an active ingredient embedded in a matrix of glucomannan for increased absorption when administered orally to humans. Since the reference discloses use of the composition in delaying absorption of a drug in the small intestine both by suppressing conveyance of the drug through the small intestine in the direction to the anus and suppressing diffusion of the drug in the solution due to the viscosity parameters of the composition, one of ordinary skill in the art would have envisaged embedding one or more active ingredients separately in glucomannan and providing the same to human in order to avoid any antagonistic interaction between the two compositions.

6. Claims **21-26, 28-29, 32 and 34-35** are rejected under 35 U.S.C. 103(a) as being unpatentable over Shibata (EP 835654 A1) in view of Walter (GB 2257358 A) or vice versa.

The teachings of Shibata have been discussed above. Shibata suggests making granules of the composition but does not teach the process of making the composition.

Shibata does not specifically disclose providing first and second composition, although the reference suggests that more than one active can be included in the composition.

Walter discloses a composition comprising vitamins, enzymes, coenzymes, minerals, trace elements and/or microorganisms that are embedded, separately with regard to function in carrier substances with formation of protective films against harmful

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effects so that, with sufficient moisture absorption, **in vivo and in vitro biocatalytic processes can be initiated and controlled**. Suitable protective substances are preferably sodium salts and potassium salts of silicic acid and nonionic polysaccharides, in particular from the family consisting of the galactomannans (page 2, Paragraph 2 and **claim 5**).

The process of mixing and drying is depicted on page 4, paragraph 4, page 7, paragraph 1 and example 2). It is further disclosed that the **granulation** can be influenced by the spraying rate and the enzyme powders are obtained in a relatively narrow particle size ranges after drying (page 8, paragraph 1).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the process of making a composition comprising active ingredient embedded in glucomannan which are functionally separated from each other as taught by Walter in the teachings of Shibata because Walter teaches that such composition helps in controlled biocatalytic processes. One of ordinary skill would have been motivated to do so because Shibata teaches oral administration of composition comprising active ingredient in glucomannan for controlled and gradual absorption of the drug over a prolonged time period and Walter teaches process of making such composition comprising active ingredient embedded in glucomannan.

It would have been obvious to one of ordinary skill in the art at the time of instant invention to formulate two compositions independently comprising similar or different active ingredients embedded in glucomannan as taught by Walter because Walter teaches that such preparation provides functionally separated compositions with

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controlled in-vivo bioactive processes once administered. Since Shibata suggests including one or more active preparations in glucomannan and Walter teaches method of making such preparation, one of ordinary skilled in the art would have had reasonable expectation of success in preparing and administering to humans, first and second active agents functionally separated due to glucomannan with no antagonistic interactions.

Response to Arguments

7. Applicant's arguments with respect to claims **21, 23-26, 28-29, 32 and 34-35** have been considered but are moot in view of the new ground(s) of rejection.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-0580. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For

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more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Snigdha Maewall/

Examiner, Art Unit 1612

/Gollamudi S Kishore/

Primary Examiner, Art Unit 1612